Novartis Methodological Note

on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the 'EFPIA Code on Disclosure of Transfers of Value' and/or 'MedTech Europe Code of Ethical Business Practice' for Alcon.

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Last Update: April 2018

Version: 4.0; this document replaces previous drafts and editions.

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1. Reference to National Transparency Laws and Regulations

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies, Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs) related to prescription-only medicines[1] by establishing a single, consistent transparency standard in Europe for disclosing ToVs across its divisions and European countries, by following the EFPIA transparency requirements and requirements set in local transparency laws.

As a Novartis Company and member of the local EFPIA Association (AIFP), Alcon Pharmaceuticals (Czech Republic) s.r.o. / Novartis s.r.o. complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with the:

- National transposition of the EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organizations 2 : **AIFP Code on Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organizations** (Approved by the AFIP General Meeting on 21 November 2013, last revision on 23rd May 2014)

- Alcon Pharmaceuticals (Czech Republic) s.r.o. signed the agreement package Data Processing Agreement Disclosure dated on 4th of November with AIFP to join the central platform for Disclosure in the Czech Republic.

[1] A definition on the terms “HPO/HCO” and “ToVs” will be provided in Chapter 5 “Novartis’ Disclosure Recognition Methodology and related Business Decisions” of this document.

[2] The EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organization (in short: EFPIA Disclosure Code) states in Section 3.05 *(Methodology)* that “e*ach Member Company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable*”.

[2] The MedTech Europe Code of Ethical Business Practice On Disclosure Of Transfers Of Value From Medical Device Companies To Healthcare Organization and Professional Conference Organizer (in short: MedTech Disclosure Code) states in Part 2 , Chapter 2.4 *(Methodology)* that “Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category described in Section 2.2 Aggregate Disclosure. The note, including a general summary and/or country specific con-siderations,shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects,currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This Methodology Note shall be made available upon request by an interested party.”.

- Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.

Local AIFP prepared the AIFP Methodology on Disclosure. The aim of this document is to provide readers of disclosed data with further information about methodologies used when disclosing Transfer of Values. As all data are disclosed on the central platform, one common methodological note covering almost all areas that need to be clarified was prepared. However, some parts of the methodology, not strictly specified by this methodological note, may slightly differ among companies and each company shall therefore publish its own methodology as well.

Alcon as a member of **MedTech Europe** (representing In-Vitro Diagnostics and Medical Devices manufacturers operating in Europe) complies with obligation of Disclosure Guidelines which is an integral part of the **Code of Ethical Business Practice** (the "Code").

- Under the Code, Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in educational conferences organised by third-parties as of 1 st January, 2018.
- Medical Education may be supported through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. Educational Grants must be publicly disclosed and documented.
- For the avoidance of doubt, all funds provided by a Member Company for the advancement of genuine educational purposes to a Professional Conference Organiser ("PCO"), acting independently of any Healthcare Organisation, fall under the scope of the Disclosure Guidelines and are subject to the same conditions as Educational Grants. Whenever the Disclosure Guidelines refer to Healthcare Organisations, these shall also include Professional Conference Organisers.

Alcon shall disclose an aggregate amount related to any of the categories set forth below:

a) Educational Grants to support Third Party Organised Events (including Support for HCP Participation at Third Party Organised Educational Events) and,

b) Other Educational Grants to Healthcare Organisations (including Scholarships, Fellowships and/or Grants for Public Awareness Campaigns).

(Note: Transfers of value are not included in the definition of Educational Grants. ToV are not within the scope of the Code´s Disclosure Guidelines).

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2017 Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. Disclosure Report based on AIFP template requirements. Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o.'s position is based on the interpretation of the current version of the EFPIA Disclosure Code, MedTech Disclosure Code aligned with local transparency laws and locally transposed EFPIA Disclosure Code into AIFP Disclosure Code and with the requirement set forward by the MedTech.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. in order to identify, collect and report ToVs for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code.

Alcon as a Member Company of MedTech shall create a note summarising the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants, as applicable. This methodology note shall be made available upon request by an interested party.

These disclosure recognition methodologies and business decisions include but are not limited to:

- Scope of Alcon Pharmaceuticals (Czech Republic) s.r.o.'s/ Novartis s.r.o.´s disclosure on ToVs (Chapter 4)
- Treatment of cross-border (Chapter 5.1)
- Handling of ToV dates for direct or indirect ToVs (Chapter 5.2)
- ToVs categories according to the EFPIA disclosure (Chapter 5.2)
- Measures taken to ensure compliance with Data Privacy requirements (Chapter 6)
- Financial aspects (Chapter 7)
- Publish Data (Chapter 8)
- Code of Ethical Business Practice (MedTech)

3. Novartis' Commitment and Responsibility for Disclosure

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies and HCPs/HCOs associated with ToVs related to prescription-only medicines, and medical devices.

Novartis establishes a single, consistent transparency standard for disclosing ToVs in all EFPIA countries.

Moreover, MedTech Europe created a single platform (EthicalMedTech website) for Member Companies to disclose ToVs in MedTech Europe geographic area[3].

4. Scope of the Novartis' Disclosure on Transfers of Value

This 2018 Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure Code - AIFP Disclosure Code and MedTech Disclosure Code. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines , OTC medicines and food supplements and medical devices disclosed by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 3 of the EFPIA Disclosure Code and ToVs for educational grants described in Chapter 4, Section 3 of the MedTech Disclosure code. Further details on the disclosure scope will be provided in Chapter 4 of this document.

The legal definition of 'prescription-only medicine' is pursuant to the definition stated in local pharmaceutical regulation issued by State Institute for Drug Control. ToVs related to a group of products that includes prescription-only medicines (e.g. combination products/diagnostics and medicinal products), OTC producsts and medical devices are reported in total following the disclosure requirements of the EFPIA Disclosure Code.

In summary:

- this 2018 Disclosure Report – AIFP Disclosure Report covers direct and indirect ToVs, payments, in kind or otherwise, made to HCPs/HCOs in connection with the development and sale of prescription-only medicinal products, OTC medicines and medical devices, whether for promotional purposes or otherwise.

- The 2018 Alcon Pharmaceuticals (Czech Republic) s.r.o. MedTech Disclosure Report covers provision of funds for the support and the advancement of genuine medical education of HCP, patients and/or the public on clinical, scientific and/or health care topics relevant to the therapeutic areas as educational grants.

[3] The MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where Member Associations are located.

Excluded from disclosure are items such as items of medical utility (governed by Article 9 of the EFPIA HCP Code), meals and drinks (governed by Article 10, especially Section 10.05 of the EFPIA HCP Code), medical samples (governed by Article 16 of the HCP Code) or which are part of ordinary course purchases and sales of medicinal products by and between a Member Company and HCP or HCO.

In this/these reports, Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. discloses the amounts of value transferred by type of ToVs with data coverage from **January 1st 2017 to Dec 31st 2017.** Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. disclosure is performed for the full calendar year 2017.

Whenever possible, Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis follows the principle of disclosure on individual HCP/HCO level, to ensure that each Recipient is referred to in such a way that there is no doubt as to the identity of the HCP/HCO benefitting from the ToVs. Aggregate disclosure is only used for non Research and Development ToVs.

Alcon Pharmaceuticals (Czech Republic) s.r.o. Transfer of Values are reportable in the form of aggregate disclosure for respective divisions for the disclosure cycle of 2018.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. - Transfer of Values follows the principle of disclosure on individual HCP/HCO level. For individual HCP disclosure is necessary to obtain the consent based on the Czech law on protection of personal data. HCP who will refuse to give the consent will be disclosed on aggregate level.

With regards to the Novartis portfolio transition Alcon ophthalmic pharmaceuticals business to move to Pharmaceuticals Division and mature products business move from Pharmaceuticals Division to Sandoz division the following is applicable: the entity paying for the engagement of the HCP reports the relevant ToV.

5. Novartis' Disclosure Recognition Methodology and Related Business Decisions

This chapter represents the central pillar of this Methodological Note. It provides comprehensive information on the terminology definitions, recognition methodology and business decisions that affected how the published ToVs data was established for each category of the disclosure report.

Alcon Pharmaceuticals (Czech Republic) s.r.o. /Novartis s.r.o. applies the definition of the HCP/HCO as outlined in the EFPIA Disclosure Code Schedule 1 (Scope - § 4) - pursuant to the AIFP disclosure code.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.

In accordance with EFPIA Disclosure Code Schedule 1 and pursuant to the national AIFP Disclosure code, ToVs to an HCP/HCO are disclosed in the country where the Recipient's primary practice is located, independent of whether the ToVs occurred inside or outside that country. The physical address where the HCP has his primary practice or the principal address of an HCO is used as the deciding factor when determining in which country the data should be disclosed.

5.1 Definition of Direct and Indirect Transfer of Values

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of ToVs as outlined in EFPIA Disclosure Code schedule 1.01 - pursuant to the definition in the AIFP Disclosure Code.

According to the EFPIA Disclosure Code schedule 1, the following definitions apply throughout this report:

- Direct ToVs are defined as those ToVs, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.
- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of a Novartis affiliate for the benefit of HCP/HCO where the Novartis affiliate knows or can identify the HCP/HCO that benefits from the ToVs.

In general, ToVs are reported at the level of the first identifiable Recipient which falls under the EFPIA definition of an HCP/HCO. To the extent possible, disclosure is made under the name of the individual HCP or at the HCO level, as long as this could be achieved with accuracy, consistency and compliance with the EFPIA Disclosure Code and pursuant to the to definition in the AIFP disclosure code. Where a ToV was made to an individual HCP rendering services on behalf of an HCO indirectly via this HCO, such ToVs are only disclosed once on either Recipient level.

Generally, ToVs to HCPs via an HCO are disclosed at the first level Recipient (HCO), or exceptionally at second level Recipient as mentioned in Section 5.3.2.1, if a contract with an HCO specifies that part of the amount must be used to engage HCPs nominated by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. When a tripartite contract exists between Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. an HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. holds a contract with a non-HCO Third-Party vendor acting on behalf of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. and who is contracting independent HCP/HCO to provide a reportable activity, ToVs are disclosed at the individual subcontracted HCP/HCO level, unless the HCP/HCO must remain unknown in order to comply with good market practices or Novartis internal rules.

ToVs from distributors of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. to HCPs/HCOs whose primary practice is in an EFPIA country must be disclosed if the distributor is making a ToV on behalf of Alcon Pharmaceuticals (Czech Republic) s.r.o. (influencing the promotional activities and selection of Recipient). ToVs to HCPs/HCOs made through a Continuous Medical Education (CME) non-HCO provider are disclosable if the 3rd party CME provider is acting on behalf of Alcon Pharmaceuticals (Czech Republic)

s.r.o./Novartis s.r.o (and Alcon Pharmaceuticals (Czech Republic) s.r.o./ Novartis s.r.o influenced choice of HCPs/Faculty).

According to the Medtech Europe Code of Ethical Business Practice Part 1, Section 6 the following definition applies:

> Member Companies may provide financial and/or in kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of the Code.

5.2 Definition of Cross-border Transfer of Values

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of cross-border ToVs as being a Transfer of Value to an HCP/HCO that occurred outside the country where the Recipient has its primary practice, principal professional address or place of incorporation provided that this country is an EFPIA and MedTech regulated countries.

In general, such ToVs are disclosed in the country where the Recipient has its principal practice, principal professional address or place of incorporation - pursuant to the definition in AIFP Disclosure Code.

5.3 Transfer of Value Categories According to the EFPIA Disclosure

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o applies the EFPIA definition of the ToVs categories as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to the definition in the AIFP Disclosure Code (see Annex 1).

The following categories constitute the EFPIA Disclosure Template for the 2018 Disclosure Report (AIFP Disclosure Report):

- Donations and grants to an HCO
- Contribution to costs related to events to an HCO/HCP, such as:
  - Sponsorship agreements
  - Registration fees
  - Travel and accommodation
- Fees for service and consultancy to an HCO/HCP
  - Fees for service and consultancy
  - Expenses related to fees for service and consultancy
- Research and development

Details on the recognition methodology and business decisions affecting how the published ToVs data was constructed for each category can be found in the subsequent sub-chapters.

5.3.1 Transfer of Values Related to Donations and Grants

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of the “Donations and Grants” category as outlined in EFPIA Disclosure Code Article 3.01 – pursuant to the definition in AIFP disclosure code (see Annex 1).

Grants to a hospital/university department or teaching institution are disclosed in the name of the legal entity that is the Recipient of the ToVs – this may be the hospital, university or independent department within these organizations.

ToVs to a charitable organization are disclosed under the “Donations and Grants” category in the name of the benefitting HCO if the charitable organization falls under the EFPIA definition of a benefitting HCO. Charitable product donations made to HCOs in the context of humanitarian aid are also disclosed in the “Donations and Grants” category.

When grant requests from HCOs include explicit support for publication, then these ToVs are disclosed in the “Donations and Grants” category.

5.3.2 Transfer of Values Related to Contribution to Costs of Events

Events are defined as promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including but not limited to advisory board meetings, visits to research or manufacturing facilities, and planning, training or conducting of investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of Alcon Pharmaceuticals (Czech Republic) s.r.o./ Novartis s.r.o. pursuant to schedule 1 of the EFPIA Disclosure Code.

ToVs to participating HCPs/HCOs related to such events falling under the definition above are disclosed in the “Costs of Events” sub-categories “Sponsorship Agreements”, “Registration Fees” or “Travel and Accommodation”. ToVs that by exception fall into the “Fees for Service and Consultancy” or “Research and Development” categories are outlined in the respective Chapters 5.3.3 and 5.3.4.

5.3.2.1 Transfer of Values Related to Contribution to Costs of Events – Sponsorship Agreements

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of the “Sponsorship Agreements” category as outlined in EFPIA Disclosure Code Article 3.01, following the principle that “Sponsorship Agreements” are formalized in contracts that describe the purpose of the sponsorship and the related direct or indirect ToV – pursuant to the definition in AIFP Disclosure Code (see Annex 1).

In general, indirect sponsorship of an HCP through an HCO is disclosed under the “Sponsorship Agreements” category as payment to the HCO as first level Recipient of the ToV. This applies to the following categories: ToVs related to intermediaries selecting the faculty who acted as speakers or faculty at an event; ToVs related to advertising space, sponsoring of speakers/faculty, satellite symposia at congresses, courses provided by HCOs.

ToVs made through a professional conference organizer (PCO) as intermediary e.g. for the hire of booths or stand space on behalf of an HCO, are disclosed as ToVs either in the "Sponsorship Agreements" category or as "Fees for Services and Consultancy" – depending on the nature of the spend, in the name of the sponsored HCO as benefitting Recipient.

If the contract requires the HCOs to use some of the amount to invite a number of HCPs selected by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. to an event, the ToV is split and disclosed based on the ToVs category the amount was used for ("sponsoring agreements" of speakers/faculty; "registration fees" or "travel and accommodation') individually in the name of each HCP.

If an intermediary organized an event with sponsorship of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. on behalf of more than one HCO, the ToV is disclosed based on the actual ToV allocated to each benefitting HCO wherever possible. In cases where it was not possible to accurately allocate the ToVs to each HCO involved in the event, it was assumed that all HCOs had similar levels of involvement. In consequence, the ToV was divided by the number of HCOs, which would each be reported as having received their equal share of the ToVs.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. discloses ToVs related to preceptorships considering that such non-promotional independent "practical" training offered to HCPs by other HCPs or HCOs – typically in a specific disease area at a reputed teaching institution (faculty of medicine, university, university hospital) – falls under the definition of "Events" and is disclosed in the name of that contracting entity.

5.3.2.2 Transfer of Values Related to Contribution to Costs of Events – Registration Fees

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of the "Registration Fees" related to cost of events categories as outlined in EFPIA Disclosure Code Article 3.01 – pursuant to the definition in the national AIFP disclosure code.

In general (and for all types of events), whenever registration fees were charged for an event organized or sponsored by or on behalf of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o., they are disclosed in the name of the benefitting HCP or HCO. The total amount of registration fees paid in a given year to a HCO should be disclosed on an individual basis (in the name of the HCO) under "Contribution to Costs of Events". The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient is disclosed on an individual basis (in his/her name) under "Contribution to Costs of Events".

ToVs related to virtual congresses (e-congresses) should be reported as actual spend. Exception applies where event is significantly undersubscribed. In such case the nominal value/ fair market value is reported. Spend is disclosed under the aggregate HCPs "Registration Fees" category.

5.3.2.3 Transfer of Values Related to Contribution to Costs of Events – Travel & Accommodation

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of the "Travel and Accommodation" related to cost of events categories - pursuant to the definition in AIFP disclosure code.

ToVs covered under the "Travel and Accommodation" category include costs of transportation (e.g. flights, trains, buses, taxis, etc., car hire tolls, parking fees) and accommodation (e.g. hotel, apartment, etc.).

In general, ToVs related to travel and accommodation are disclosed at first level Recipient basis. If the ToVs are made through an HCO or intermediary (third party), it will be disclosed at individual HCP level whenever possible (see Chapter 5.11).

ToVs related to travel and accommodation for a group of HCPs such as group transportation by bus are disclosed on an aggregate basis. If the mass transportation is shared by a group of HCPs who have their primary practice in different countries, the ToVs are disclosed in aggregate with the total cost divided equally among the planned number of benefitting HCPs per country.

In case the benefitting HCP partly bears the costs related to travel and accommodation, the net amount of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. payment offset by payment from HCP is disclosed as ToV under the "Travel and Accommodation" category in the name of the HCP.

5.3.3 Transfer of Values Related to Contribution to Fees for Service and Consultancy

5.3.3.1 Transfer of Values related to Contribution to Fees for Service and Consultancy – Fees

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of the "Fees for Service and Consultancy" category as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to the definition in AIFP Disclosure Code.

ToVs covered under the "Fees for Service and Consultancy" category, whether made directly or through a third party to an HCP/HCO, include but are not limited to services performed in connection with third-party congresses, speakers' fees, speakers' trainings, medical writing, data analysis, development of education material, interviews e.g. on Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. has formalized such collaboration in a contract describing the purpose of ToVs. In general, the ToVs received by the contracting entity – which may be an HCP, a legal entity owned by an HCP

(considered an HCO under the EPFIA Disclosure Code) or an HCO – are disclosed under the "Fees for Service and Consultancy" category in the name of that contracting entity.

As mentioned in Chapter 5.3.2.1.3, ToVs made through a PCO as intermediary (e.g. for the hire of booths or stand space on behalf of an HCO), are disclosed as ToVs either in the "Sponsorship Agreements" category or as "Fees for Services and Consultancy" depending on the nature of the spend, in the name of the sponsored HCO as benefitting.

ToVs related to the educational activities to HCPs (seminars, events) organized by PCO only will be disclosed in separate CME Disclosure based on the decision of local AIFP. It will be disclosed at AIFP page at the section Congresses.

ToVs related to market research studies for which the identity of the Recipient was known to Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o., are disclosed under the "Fees for Service and Consultancy" category. ToVs related to market research studies for which the identity of the HCP/HCO was not known to Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. are not disclosed as the right of the respondents to remain anonymous is embodied in market research definitions and relevant codes of conduct worldwide.

ToVs related to medical writing and editorial support made directly or indirectly to an HCO/HCP are disclosed either under the "Fees for Service and Consultancy" in the name of the benefitting HCP/HCO or under the "Research and Development" category in aggregate form – pursuant to local law and regulations, or self-regulatory codes which the Member Companies have subscribed to. The following instances of medical writing and editorial support are covered under the "Fees for Service and Consultancy" category: case studies, congress write ups, article and abstracts, manuscripts, poster, clinical management guideline, supplements.

ToVs related to the following Research and Development related activities (see Chapter 5.3.4) but when they do not fall under the definition of Research and Development ToVs as stated by the EFPIA Disclosure Code and EFPIA HCP Code Article 15 are disclosed under the "Fees for Services and Consultancy" category in the name of the benefitting Recipient, for example:

- Retrospective non-interventional studies not falling under the definition of Research and Development ToVs as per EFPIA Disclosure Code definition of Research and Development Schedule 1 and EFPIA HCP Code Article 15
- Investigator initiated trials, investigator sponsored trials and Investigator meeting, in the exceptional cased when such ToV do not fall under the definition of Research and Development mentioned above
- Activities contracted to Contract Research Organizations (CROs) where Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. makes indirect ToVs to HCPs/HCOs but not falling under the EFPIA Research and Development definition
- Project activities related to e.g. disease area, mode of action, market placement, adjudication committees, speaker programs, scientific meetings, ethics committees, steering committee and advisory board activities not in scope of the EFPIA Research and Development definition

- ToVs related to consultancy for tool/questionnaire selection or analysis and reporting of results not in scope of the EFPIA Research and Development definition

5.3.3.2 Transfer of Values related to Contribution to Fees for Service and Consultancy – Related Expenses

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. fully complies with the EFPIA definition of the "Fees for Service and Consultancy - Related Expenses" category as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to definition in the AIFP Disclosure Code.

In general, the ToVs amount related to expenses such as travel and accommodation cost associated with the activity agreed to in a "Fees for Service" or "Consultancy" contract do not constitute part of the fees itself; in consequence such ToVs are disclosed under the "Related Expenses" category in the name of the benefitting HCP/HCO.

In case such expenses were not material (e.g. of limited value), or when such expenses despite best effort could not be accurately disaggregated from the fees, such ToVs have been disclosed as part of the total amount of fees under the "Fees for Service or Consultancy" category.

5.3.4 Transfer of Values Related to Research and Development

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of the "Research and Development" category as outlined in EFPIA Disclosure Code – Schedule 1, the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice, the definition of clinical trials and non-interventional studies (as defined in Directive 2001/20/EC and Section 15.01 of the HCP Code) - pursuant to definition in AIFP Disclosure Code.

ToVs **related to the following Research and Development activities** are disclosed under the "Research and Development" category in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code, for example:

- Activities related to the planning or conduct of non-clinical studies, clinical trials or prospective non-interventional studies and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study (Section 15.01 of the HCP Code).
- IIT (Investigator initiated trials) and IST (Investigator sponsored trials - since, although not initiated by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o., they may benefit from Alcon Pharmaceuticals (Czech Republic) s.r.o. /Novartis s.r.o.
- Post marketing trials, investigator meetings - in which case the total ToV amount is disclosed and in case of participating HCP from other countries, the total actual cost per meeting (incl. infrastructure, travel, logistic and with exclusion of meals whenever possible) is divided by the number of participants per country of practice

- Activities contracted to CROs, where Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o makes indirect ToVs to HCPs/HCOs falling under the definition of Research and Development
- ToVs related to early stage research if falling under the definition of Research and Development in the EFPIA Disclosure Code

In case ToVs relating prospective and retrospective non-interventional studies cannot be distinguished, all non-interventional studies are disclosed on an individual basis.

ToVs made by or on behalf of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. **related to consultancy activities** are disclosed under the **"Research and Development" category** in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code: consultancy activities related to the planning/conduct of non-clinical studies, clinical trial or prospective non-interventional studies, ethics committees, steering committee and advisory board activities related to the planning or conduct of non-clinical studies, clinical trial or prospective non-interventional studies, adjudication committees, speaker programs, scientific meetings.

ToVs related to **licensing fees** paid for the use of Clinical/Health Economics and Outcomes Research questionnaires and tools, if the questionnaires and tools are intended for use with an Research and Development project/study are reported in aggregate form under the "Research and Development" category.

As defined in Chapter 5.3.3, ToVs related to **medical writing and editorial support** made by or on behalf of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. to an HCO/HCP are disclosed either under the "Fees for Service and Consultancy" category in the name of the benefitting HCP/HCO or under the "Research and Development" category in aggregate form – pursuant to AIFP Disclosure Code (see Annex 1). The following instances of medical writing and editorial support are covered under the "Research and Development" category: investigator's brochure (trials), clinical study report (trials), clinical report, safety report; generally all types of medical writing related to clinical trials or related to Research and Development activities.

5.4 Transfer of Value Categories According to the MedTedch Disclosure Code

Alcon Pharmaceuticals (Czech Republic) s.r.o. applies the MedTech definition of the ToVs in the Definition of "Educational Grants" as outlined in the MedTech Disclosure Code in Part 1, Chapter 4, Section 3.

The following categories constitute the MedTech Disclosure template for the 2018 Alcon Pharmaceuticals (Czech Republic) s.r.o. MedTech Disclosure Report:

- Educational grants to support Third Party Organised Events (including support for HCP participation at Third Party Educational Events)
- Other educational grants to HCOs (including scholarships, fellowships and/or grants for public awareness campaigns)

5.4.1 Transfer of Values Related to Educational Grants to support Third Party Organised Educational Events

Alcon Pharmaceuticals (Czech Republic) s.r.o. applies the MedTech definition of the "Educational Grants" category as outlined in MedTech Europe Code of Ethical Business Practice Part 1, Chapter 4, Section 3.a, following the general principle that any Third Party Organised Educational Event supported by way of an educational grant from a Member Company to a HCO must:

- Comply with Part 1, Chapter 1 "General Criteria for Events"of the MedTech Disclosure Code, and
- Where applicable, have approval via the Conference Vetting System (CVS) (http://www.ethicalmedtech.eu/conference-vetting-system/)

5.4.1.1 Support for HCP Participation at Third Party Organsed Educational Events

Where the educational grant is provided for the purpose of supporting HCPs' attendance at Third Party Organised Educational Events, the HCO receiving the grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written grant agreement.

5.4.1.2 Support for Third Party Organised Educational Events

Where the prospective beneficiary of an educational grant is the organizer of the Third Party Organised Educational Event and is also a HCO, the recipient HCO shall be solely responsible for:

- The programme content;
- The selection of faculty; and
- The payment of faculty honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of faculty and this shall be reflected in the written grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

5.4.2 Transfer of Values Related to Other Educational Grants to Helthcare Organizations

Alcon Pharmaceuticals (Czech Republic) s.r.o. applies the MedTech definition of the "Other Educational Grants" category as outlined in MedTech Europe Code of Ethical Business Practice Part 1, Chapter 4, Section 3.b and c, following the general principle for:

5.4.2.1 Scholarship and Fellowship:

Member Companies may provide educational grant on a restricted basis in the form of grants for scholarships and fellowships to support advancement of genuine medical education of HCPs.

Only HCOs where HCPs are in training shall be eligible to request and/or receive such educational grants. A Member Company shall not provide educational grants to support scholarships and fellowships upon request of individual HCPs. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the educational grant and this shall be reflected in the written grant agreement between the Member Company and the recipient HCO.

5.4.2.2 Grants for Public Awareness Campaigns:

Member Companies may also provide educational grants on a restricted basis to HCOs for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved.

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. to ensure compliance with data privacy regulations, rules on consent collection and managing of relevant information in compliance with relevant internal rules, data privacy laws and regulations.

Based on loal AIFP Methodology on Disclosure there are two possibilities of consent collection:

- closing a written agreement including specific legal provisions. According to the standpoint of the Office for Personal Data Protection which AIFP received in reply to its questions, it is possible to make use of a legal dispensation from the obligation to obtain consent from each Healthcare Professional, provided an agreement between the Healthcare Professional and an AIFP Member Company contains a provision to the effect that processing of personal data is necessary for the purposes of the agreement (see the provisions of Section 5(2)(b) Act No. 101/2000 Coll., the Protection of Personal Data, as amended). If such agreement is concluded (in writing), the Healthcare Professional's consent is nor needed and cannot be therefore revoked.),
- obtaining the consent from the healthcare professional with processing of personal data.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. obtaining the consent from the healthcare professional.

6.1 Safeguarding Measures to Address Lawful Collection, Processing and Transfer of HCPs´ Personal Data

Data privacy refers to the individual's fundamental right to control the use of, access to and disclosure of information that describes or identifies the individual ("personal Information"). To fulfil the transparency disclosure requirements, it is necessary to collect, process and disclose such personal data within and outside of Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by the Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. (publishing affiliate). The disclosure of such personal information by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. is at all times limited to the intended purposes.

In case personal data had to be transferred from countries to the central Novartis Transparency data repository manually (e.g. excel) or via interfaces, applicable local regulations for the transfer were assessed at local level and managed accordingly. Where required, the transfer of data to a third country (outside the EU/EEA) was approved by the data controller´s Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. country data protection authority (Office for Personal Data Protection).

6.2 Consent Collection

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. discloses on individual HCP/HCO level. For individual HCP disclosure is necessary to obtain the consent based on the Czech data privacy laws. HCP who will refuse to give the consent will be dislosed on aggregate level.

Alcon Pharmaceuticals s.r.o. discloses completely in aggregate value based on Novartis exception applicable to the current disclosure cycle as follows: No consent collection was required for HCPs/HCOs since Alcon Pharmaceuticals (Czech Republic) s.r.o. performs an aggregate disclosure during the 2018 disclosure cycle for ToV categories.

Consent for the publication of the ToVs was obtained and documented as such before disclosing the data on an individual HCP level, The HCOs, i.e. legal entities are not subject to personal data protection under the law and therefore the consent collection is not required. Consent management procedures were conducted in alignment with the internal data protection procedure/policy.

Consent was obtained either on Recipient level for all ToVs during a given period of time not shorter than one full year or on spend level for each interaction or single ToVs. Alcon Pharmaceuticals s.r.o. decided to obtain the consents once for 3 year period based on The Czech law on protection of personal data. Novartis s.r.o. decided to obtain new consents for 2018 in case that HCP did not agree with the Disclosure. In case that the Novartis globally will modify the rules for disclosure in the future, the consents will be obtained from each individual HCP again.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. does not accept partial consent or split disclosure.

In case consent was either not given by the Recipient or not documented sufficiently to prove the existence of consent, ToVs are disclosed on aggregate level only.

In the event of death of an HCP by the time of disclosure (by the publication date) the ToV is reported in aggregate.

HCP has a right to withdraw the consent. Consent withdrawal has been assessed according to the relevant The Czech law on protection of personal data. Regulation that applies: The Czech law on protection of personal data 101/2000 as amended.

7. Financial Aspects

This chapter focusses on the financial aspects related to recognition methodology and business decisions associated with the collection and disclosure of the ToVs information.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. complies with Novartis (divisional) accounting principles and the financial disclosure methodology - pursuant to definition in AIFP Disclosure Code.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. decided to apply the following rules for ToVs payment dates based on type of ToVs: direct ToVs are disclosed based on the date the payment has been cleared via banking system. Indirect ToVs related to events such as congresses for which the dates of (in kind) expenses differ from the date(s) the event took place, are disclosed using the date of the last day of the event.

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed.

Where income tax or equivalent is withheld by Alcon Pharmaceuticals (Czech Republic) s.r.o. on amounts earned by the HCP then the ToV will include these amounts.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. ToVs will be disclosed in the local currency of the country where the disclosing entity is located. For direct and indirect TOVs, the foreign currency is converted to the local currency of the disclosing entity based on the transaction date. For cross-border TOVs, the foreign currency is converted to the local currency of the disclosing entity based on the average rate for the month in which the TOV occurred, using the Novartis Treasury rates.

The responsibility for disclosing and reporting ToVs is with the disclosing entity country where the Recipient's principle practice is located. In the case of payments made by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. to an HCP or HCO, and then cross-charged to another Novartis company, or made by another Novartis company to an HCP

or HCO and then cross-charged to Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o., the ToV information is provided by the original paying entity to the disclosing entity. The ToV will only be recognized once in the country where the Recipient's principle practice is located.

In case of cross-border ToVs as defined in Chapter 5.2, direct ToVs will be recognized when the payment has been cleared via the banking system and indirect ToVs will be related to the end date of the event. This information will not be available to the disclosing country immediately and so there may be cutoff recognition issues over year end. If ToV information is not provided to the Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. with adequate time to be included for disclosure in the expected reporting year, it will be disclosed in the immediate following year.

In case of multi-year contracts, ToVs are recognized based on the date the payment has been cleared via the banking system. If, for example, the HCP/HCO has entered into a contract with a term of three years and receives equal annual payments, these ToVs of an amount of one third of the total contract value would be disclosed each year in the appropriate category.

- When affiliate realizes that the published disclosure report is missing data, i.e. ToV has not been reported, missed ToV shall be reported in aggregate/ on individual level, based on consent level in a revised (updated) report in the same disclosure cycle. In case affiliate includes ToV from previous year in current year disclosure, this must be mentioned in the methodological note.

8. Published Data

Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. applies the EFPIA definition of "Form of Disclosure" as outlined in EFPIA Disclosure Code Article 2 - pursuant to the definition in the AIFP Disclosure Code.

This 2018 Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis AIFP Disclosure Report has been officially published on June 30th.

Disclosures are made on an annual basis within 6 months after the end of the relevant full calendar year.

Updates of published data are conducted on at least quarterly basis to allow for reflection of data updates or consent withdrawal after disclosure submission.

Also, Alcon Pharmaceuticals (Czech Republic) s.r.o.applies the MedTech definition of "Form of Disclosure" as outlined in MedTech Disclosure Code Part 2, Chapter 3.

Disclosures shall be made on the EthicalMedTech website (www.ethimedicalmedtech.org) unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Section 1.2 "Applicability of these Disclosure Guidelilnes". Member

Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, MedTech Europe shall not be held liable for:

- maintaining, correct-ing, deleting the published data nor
- for the storage of data after the three years period of disclosure in the public domain.

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

Pre-dislosure process for Novartis s.r.o. includes the predisclosure letter with all ToV related to the individual HCP with the consent printed directly from the internal disclosure system. Novartis s.r.o will ask for the HCP´s confirmation about all ToV with Novartis s.r.o for a specific year. HCP has a right to withdraw the consent in written to the common address **privacy.cz@novartis.com.** Consent withdrawal is with retroactive effect and Novartis s.r.o. has to change the Disclosure report at lAIFP platform properly and as soon as possible. Dispute person´s telephone number is a part of the pre-disclosure letter. Novartis s.r.o Consent withdrawal has been assessed according to the relevant Czech data privacy laws. Regulation that applies: Law on personal data protection 101/2000 as amended.

Alcon: Pre-disclosure activity is not applicable generation of 2016 report due to aggregate reporting. Pre-disclosure is applicable only for HCP´s where “disagreement consent” was provided. For disclose purposes in 2017 special common address **privacy.cz@alcon.com** will be established and managed with regards to all applicable regulations.

Internal document “Local Xpend Methodologies Guideline” includes detailed disclosure process description based on local specifics: inputs, ouputs, responsibilities, sources, procedures, methodologies to comply with all applicable requirements.

Publication is made via the following disclosure platform – central AIFP platform:

(http://www.aifp.cz/en/ethical-conduct/disclosure/)

The links and information about the transparency cooperation and Disclosure will be also at local affiliate website:

- http://cz.alcon.com/
- http://www.novartis.cz/spolecenskaodpovednost/index.shtml (with link to Alcon website).

The platform chosen fulfills the recommendation of the EFPIA Disclosure Code as being a platform accessible in the country where the Recipient has the primary practice and following the local laws or regulations of the country where the Recipient has their practice. All EFPIA Disclosure Reports published by Alcon Pharmaceuticals (Czech Republic) s.r.o./Novartis s.r.o. and any other Novartis affiliate in the Czech Republic are not published on the same platform.

This data will remain published for 3 years in public domain and stored for a minimum of 5 years on record by the publishing affiliate.

- Specification based on local AIFP Disclosure Code:
  - Disclosures shall be made in Czech and English
  - Doctor's unique identifier is a registration number assigned by the Czech Medical Chamber; for pharmacists it is a registration number assigned by the Czech Chamber of Pharmacists. The unique identifier of a Healthcare Organisation is IČ (IN)
  - HCP – physical entity – who can be identified based on the registration number of the Czech Medical Chamber will be registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

MedTech (for Alcon) specified following requirements regarding to reporting:

Member Companies need not report the same information twice due to being bound by national laws, regulations or professional codes.

- Disclosures shall be made on an annual basis and each Reporting Period shall cover a full calendar year.
- Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period.
- The disclosures shall be made public at the time of publication. The time of publication is the 31st August of the year of the relevant time of disclosure.
- For consistency purposes, disclosures made pursuant to the Disclosure Guidelines shall be made in English using the template set forth in the Annex 1.
- Disclosures shall be made on the EthicalMedTech website unless the Member Company is already bound by national laws, regulations or professional codes, see Section 1.2 Applicability of the Disclosure Guidelines. Member Companies will remain liable for the accuracy of the disclosed data.
- Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.
- Member Companies shall make available to Healthcare Organizations upon request any data concerning their common contractual relations published in accordance with the Disclosure Guidelines at any time while the disclosed information remains in the public domain (as stated in Section 3.3 Time of Publication of the Code).

9. References

This chapter contains references to internal and external sources for further reading and documentation purpose.

- Alcon Pharmaceuticals (Czech Republic) s.r.o. website (cz.alcon.com)
- Novartis s.r.o. website (https://www.novartis.cz/o-nas/spolecenska-odpovednost-v-cr)
- National EFPIA Member Association websites (www.efpia.eu) specifically AIFP website (www.aifp.cz)
- Direct link to the EFPIA Disclosure platform (http://www.efpia.eu/disclosure)
- Direct link to the AIFP Disclosure platform (http://www.aifp.cz/en/ethical-conduct/disclosure/)
- MedTech Europe Code of Ethical Business Practice (http://www.medtecheurope.org/legal-and-compliance/code)

10. Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on the Schedule 1 of the EFPIA Disclosure Code and Medtech Disclosure Code /AIFP Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations whenever possible:

- **Conference Vetting System (CVS):** means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.

- **Contract Research Organization (CRO):** an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.[4]

- **Educational Grants:** means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

- **Healthcare Professional (HCP):**

    - **EFPIA:** Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her

[4] Source www.wikipedia.org

professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

- **MedTech:** means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.

- **Healthcare Organization (HCO):**

  - **EFPIA**: Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCP provide services.

  - **MedTech**: means any legal entity or body (irrespective of its legal or organisational form) that is a -healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, -recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching –institution or learned or professional society (except for patient organisations); or through which one or more Healthcare –Professionals provide services.

- **MedTech Europe Code of Ethical Business Practice:**

  - MedTech Europe is the only European trade association representing the medical technology industry from diagnosis to cure and represents In-Vitro Diagnostics and Medical Devices manufacturers operating in Europe.The MedTech Europe Code of Ethical Business Practice regulates all aspects of the industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), to ensure that all interactions are ethical and professional at all times and to maintain the trust of regulators, and – most

importantly – patients. It became binding for MedTech Europe corporate members on 1st January 2018.

- **Member Associations:**

  - **EFPIA:** Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA codes of practice, including the EFPIA HCP Code, the EFPIA Patient Organization Code and the EFPIA HCP/HCO Disclosure Code.

  - **MedTech** : means all full and associate national association members of Eucomed and/or EDMA (or as applicable MedTech Europe) ("**Member Associations**"), as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.

- **Member Companies:**

  - **EFPIA:** Collectively, "corporate members" (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organization) and any companies affiliated with corporate members or their subsidiaries. Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

  - **MedTech** : means all full and associate corporate members ("**Member Companies**") of Eucomed and/or EDMA (or as applicable MedTech Europe) as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.

- **Professional Conference Organizer (PCO):** a company which specializes in the organization and management of congresses, conferences, seminars and similar events.[5]

- **Recipient:** Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in a country whose association is a member of EFPIA.

- **Research and Development ToVs:** ToVs to HCPs or HCOs related to the planning or conduct of (I) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional

[5] Source www.wikipedia.org

studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code).

- **Scholarships and Fellowships:** means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). “Scholars” and “Fellows” shall be understood accordingly.

- **Third Party Organised Educational Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

- **Third Party Organised Educational Conferences:** means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited -continuing medical education providers.

- **Third Party Organised Procedure Training:** means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
    - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
    - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.
- Proctorships and preceptorships are not considered to constitute Third Party Organised Procedure Training.

- **Transfers of Value (ToVs):**

    - **EFPIA:** Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products, OTC medicines and food supplements exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an

intermediate and where the Member Company knows or can identify the HCP/HCO that benefit from the Transfer of Value.

- **MedTech:** covers provision of funds for the support and the advancement of genuine medical education of HCP, patients and/or the public on clinical, scientific and/or health care topics relevant to the therapeutic areas as Educational Grants.